

EXHIBIT H

1 UNITED STATES DISTRICT COURT
2 DISTRICT OF NEW JERSEY
3 Case No. 1:19-md-2875-RBK

4 _____)
IN RE: VALSARTAN, LOSARTAN AND)
5 IRBESARTAN PRODUCTS LIABILITY)
LITIGATION,)
6)
7)

THIS DOCUMENT RELATES TO ALL ACTIONS)
8)
9)

10 -----
11 DAY 2

12 CONFIDENTIAL

13 VIDEOTAPED DEPOSITION OF

14 DIPAK PANIGRAHY, M.D.

15 FRIDAY, SEPTEMBER 10, 2021

16 8:49 a.m. - 2:32 p.m.

17 GREENBERG TRAURIG LLP

18 ONE INTERNATIONAL PLACE, SUITE 2000

19 BOSTON, MASSACHUSETTS
20
21
22

23 Reported by: Sandra A. Deschaine, CSR, RPR,
24 CLR, CRA

25 Job No. 4769072

<p style="text-align: right;">Page 483</p> <p>1 correct?</p> <p>2 A. My opinion is on NDMA and --</p> <p>3 Q. All right. I'll be more precise.</p> <p>4 You told us that you relied on the</p> <p>5 Hidajat study to support your opinion that 12:46 PM</p> <p>6 NDMA exposure causes cancers in humans,</p> <p>7 correct?</p> <p>8 A. Correct.</p> <p>9 Q. As we've already established,</p> <p>10 Hidajat was an occupational study of factory 12:46 PM</p> <p>11 workers in the rubber industry, true?</p> <p>12 A. True.</p> <p>13 Q. The route of administration or the</p> <p>14 route of exposure to NDMA among the factory</p> <p>15 workers was inhalation, correct? 12:47 PM</p> <p>16 A. Correct.</p> <p>17 Q. And as I recall, the stated</p> <p>18 purpose of that study was to evaluate cancer</p> <p>19 mortality risks associated with occupational</p> <p>20 exposures to rubber dust, rubber fumes and 12:47 PM</p> <p>21 nitrosamines, correct?</p> <p>22 A. Correct.</p> <p>23 Q. And as Hidajat observed, rubber</p> <p>24 workers are exposed to a host of potential</p> <p>25 carcinogens in addition to NDMA, correct? 12:47 PM</p>	<p style="text-align: right;">Page 485</p> <p>1 nitrosamines that they looked at.</p> <p>2 A. Yes, then correct.</p> <p>3 Q. But the point I was trying to get</p> <p>4 at is, they did not consider it a confounding</p> <p>5 contribution or risk of carcinogens such as 12:49 PM</p> <p>6 benzene or nathylamine; is that correct?</p> <p>7 A. When they calculated the risks of</p> <p>8 cancer mortality, they quantified the NDMA</p> <p>9 exposure using quartiles. So they related</p> <p>10 the amount of NDMA that these workers were 12:49 PM</p> <p>11 exposed to to the cancer mortality.</p> <p>12 Q. I know what they did with respect</p> <p>13 to NDMA. I asked you a different question.</p> <p>14 Let me see if I can try it again.</p> <p>15 Did the authors of the Hidajat 12:49 PM</p> <p>16 study consider the confounding contribution</p> <p>17 of risks for carcinogens such as benzene or</p> <p>18 nathylamine, both of which are prevalent in</p> <p>19 the rubber industry.</p> <p>20 A. I don't believe they looked at 12:49 PM</p> <p>21 benzene.</p> <p>22 Q. And another notable limitation of</p> <p>23 the Hidajat study is that the authors were</p> <p>24 not able or did not have the ability to</p> <p>25 control for smoking or other lifestyle 12:50 PM</p>
<p style="text-align: right;">Page 484</p> <p>1 A. Correct.</p> <p>2 Q. But some of those other</p> <p>3 carcinogens represent potential confounding</p> <p>4 exposures. Would you agree?</p> <p>5 A. Yes. However, Hidajat quantified 12:47 PM</p> <p>6 the amount of NDMA using four different</p> <p>7 quartiles to relate to the cancer mortality.</p> <p>8 Q. I understand that.</p> <p>9 But he also noted and observed</p> <p>10 that there were other -- that every subject 12:47 PM</p> <p>11 in that study was exposed to carcinogens --</p> <p>12 other carcinogens in addition to NDMA, right?</p> <p>13 A. Correct.</p> <p>14 Q. Hidajat found cancer risks</p> <p>15 associated with rubber dust, correct? 12:48 PM</p> <p>16 A. Yes.</p> <p>17 Q. Hidajat found cancer risks</p> <p>18 associated with rubber fumes, true?</p> <p>19 A. Correct.</p> <p>20 Q. And in the study, Hidajat -- the 12:48 PM</p> <p>21 authors of the Hidajat study look only at</p> <p>22 rubber dust, rubber fumes, and nitrosamines</p> <p>23 correct?</p> <p>24 A. They also looked at NDMA.</p> <p>25 Q. I'm including NDMA as one of the 12:48 PM</p>	<p style="text-align: right;">Page 486</p> <p>1 factors, correct?</p> <p>2 A. Correct, yes.</p> <p>3 Q. But nevertheless, in your report,</p> <p>4 you provide us with cumulative exposure data</p> <p>5 for NDMA from the Hidajat study, right? 12:50 PM</p> <p>6 A. Correct.</p> <p>7 Q. And I think it's at page 87 of</p> <p>8 your report, if you have it in front of you,</p> <p>9 the second full paragraph there, you suggest</p> <p>10 that workers in Quartile II had cumulative 12:50 PM</p> <p>11 exposure to 7,488 micrograms, correct?</p> <p>12 A. Yes.</p> <p>13 Q. That's -- that translates to</p> <p>14 7,488,000 nanograms, true?</p> <p>15 A. Yes. 12:51 PM</p> <p>16 Q. And workers in Quartile III,</p> <p>17 according to you and your interpretation of</p> <p>18 the Hidajat data, had cumulative exposures to</p> <p>19 14,304 micrograms, correct?</p> <p>20 A. Correct. 12:51 PM</p> <p>21 Q. And that translates to 14,304,000</p> <p>22 nanograms?</p> <p>23 A. Correct.</p> <p>24 Q. And in Quartile IV, the workers in</p> <p>25 the Hidajat study had cumulative exposure to 12:51 PM</p>

<p style="text-align: right;">Page 487</p> <p>1 23,208 micrograms of NDMA, correct?</p> <p>2 A. Yes.</p> <p>3 Q. And, again, simple math tells us</p> <p>4 that that translate to 23,208,000 nanograms</p> <p>5 of NDMA, to which the workers in Quartile IV 12:51 PM</p> <p>6 were exposed, right?</p> <p>7 A. Yes.</p> <p>8 Q. In looking at your report, you did</p> <p>9 not provide any calculation of cumulative</p> <p>10 exposure for Quartile I; is that true? 12:52 PM</p> <p>11 A. Yes. Quartile I was the baseline</p> <p>12 of the background.</p> <p>13 Q. And that baseline -- that baseline</p> <p>14 exposure, then, was less -- was less than the</p> <p>15 7,488 micrograms. Is that what I understand 12:52 PM</p> <p>16 that to be then?</p> <p>17 A. Correct.</p> <p>18 Q. Did anyone in Quartile I have an</p> <p>19 increased risk of cancer in the Hidajat</p> <p>20 study? 12:52 PM</p> <p>21 A. So what Hidajat compared, and they</p> <p>22 did actually -- you had brought up smoking.</p> <p>23 They did comment on they thought had they</p> <p>24 adjusted smoking it wouldn't have made a</p> <p>25 difference. 12:52 PM</p>	<p style="text-align: right;">Page 489</p> <p>1 right?</p> <p>2 A. Correct.</p> <p>3 Q. So workers in that study were</p> <p>4 thought to be exposed to other nitrosamines</p> <p>5 as well, right? 12:54 PM</p> <p>6 A. Correct.</p> <p>7 Q. In fact, Hidajat talks about other</p> <p>8 nitrosamines that were prevalent in the</p> <p>9 rubber industry, including NMOR, right?</p> <p>10 A. Right. In rubber dust, NDMA is 12:54 PM</p> <p>11 the most highest and -- the highest</p> <p>12 concentration of a nitrosamine in rubber</p> <p>13 dust.</p> <p>14 Q. We can talk about that, perhaps,</p> <p>15 if we have additional time. But what I'm 12:54 PM</p> <p>16 interested in trying to make clear and trying</p> <p>17 to understand, is that all the workers in the</p> <p>18 Hidajat occupational study were exposed to</p> <p>19 other nitrosamines in addition to NDMA.</p> <p>20 We know that for a fact, right? 12:55 PM</p> <p>21 A. Correct.</p> <p>22 Q. And Hidajat actually went so far</p> <p>23 as to calculate a total nitrosamine score for</p> <p>24 the individuals in Quartiles II, III and IV,</p> <p>25 correct? 12:55 PM</p>
<p style="text-align: right;">Page 488</p> <p>1 And what they did was compare</p> <p>2 Quartile II, III and IV to Quartile I, was</p> <p>3 the comparison.</p> <p>4 Q. So in Hidajat, is it your</p> <p>5 understanding in that study there's no effort 12:53 PM</p> <p>6 made to determine whether cumulative exposure</p> <p>7 to something less than 7 1/2 million</p> <p>8 nanograms over a lifetime would cause an</p> <p>9 increased risk of cancer; that wasn't the</p> <p>10 analysis that Hidajat did, right? 12:53 PM</p> <p>11 A. Correct. My understanding is that</p> <p>12 they were comparing this increased exposure</p> <p>13 to NDMA and using increased exposure from</p> <p>14 Quartile II to Quartile III was even higher,</p> <p>15 to Quartile IV was even higher, was that each 12:53 PM</p> <p>16 comparison was to Quartile I.</p> <p>17 Q. Right. So what they were looking</p> <p>18 at was whether there's an increasing risk of</p> <p>19 cancer at exposure levels above 7 1/2 million</p> <p>20 nanograms, agreed? 12:53 PM</p> <p>21 A. Correct.</p> <p>22 Q. And -- now, the numbers that you</p> <p>23 gave us for cumulative exposures from Hidajat</p> <p>24 we just talked about were strictly cumulative</p> <p>25 exposures to NDMA in that rubber industry, 12:54 PM</p>	<p style="text-align: right;">Page 490</p> <p>1 A. Correct. Yes.</p> <p>2 Q. The -- and that total nitrosamine</p> <p>3 score was even higher than the cumulative</p> <p>4 numbers that you reported to us for NDMA,</p> <p>5 right? 12:55 PM</p> <p>6 A. Yes.</p> <p>7 Q. I think if you look at -- do you</p> <p>8 have the Hidajat paper in front of you or do</p> <p>9 you need me to --</p> <p>10 A. Yes, I have it. 12:55 PM</p> <p>11 Q. Okay. Great.</p> <p>12 I think if you go to -- might be</p> <p>13 the second to the last page. It's the last</p> <p>14 page of Table 2 there, so looking at the</p> <p>15 material down at the bottom. 12:56 PM</p> <p>16 Do you see that?</p> <p>17 A. Yes.</p> <p>18 Q. All right. And it's there, where</p> <p>19 Hidajat documents the total nitrosamine</p> <p>20 scores for occupational exposures of workers 12:56 PM</p> <p>21 in Quartiles II, III and IV, right?</p> <p>22 A. Yes.</p> <p>23 Q. And what he says is that, in</p> <p>24 Quartile II, the total nitrosamines exposure</p> <p>25 for these workers is on the order of 12:56 PM</p>

<p style="text-align: right;">Page 491</p> <p>1 something greater than 10.03 micrograms, 2 right?</p> <p>3 A. Yes.</p> <p>4 Q. And in Quartile III, the exposure 5 is between 10.03 to 21.8 micrograms? 12:56 PM</p> <p>6 A. I'm not following where you are.</p> <p>7 Q. The footnotes --</p> <p>8 A. Oh, at the footnote.</p> <p>9 Q. -- down at the bottom of the page, 10 the Hidajat's paper we were talking about. 12:57 PM</p> <p>11 A. Yes, the exposure Quartile I?</p> <p>12 Q. Right. Correct.</p> <p>13 A. Yes.</p> <p>14 Q. Then you see Quartile II with the 15 exposure of 10.0 to 21.38. You see that? 12:57 PM</p> <p>16 A. Yes.</p> <p>17 Q. Quartile III lists 2138 to 442?</p> <p>18 A. Yes.</p> <p>19 Q. And usually the same calculations 20 and assumptions and methodology that you put 12:57 PM 21 in your report, you can calculate a total 22 cumulative nitrosamine exposure for the 23 rubber workers based on that data that 24 Hidajat just gave us, right?</p> <p>25 A. Correct. 12:58 PM</p>	<p style="text-align: right;">Page 493</p> <p>1 51,000 to 1 million micrograms, using the 2 same assumptions and methodology that you 3 used in your report, correct?</p> <p>4 MR. NIGH: Form objection.</p> <p>5 A. Yes. 12:59 PM</p> <p>6 BY MR. TRISCHLER:</p> <p>7 Q. So, in this -- by the way, have 8 you ever looked at any of the medical records 9 for any of the plaintiffs in this litigation?</p> <p>10 A. No. 01:00 PM</p> <p>11 Q. Have you looked at any of the 12 pharmacy records for any of the plaintiffs in 13 this litigation?</p> <p>14 A. Yes, I did have files on the 15 amount of NDMA in the valsartan tablets. 01:00 PM</p> <p>16 Q. Okay. Perhaps my question wasn't 17 clear. So I apologize for that.</p> <p>18 I was not asking you about testing 19 information that you may have received on 20 nitrosamine levels that were found in some 01:00 PM 21 valsartan. I was asking about patient 22 pharmacy records showing what medications a 23 given patient received and when and from 24 whom. That's what I was referring to as 25 pharmacy records 01:00 PM</p>
<p style="text-align: right;">Page 492</p> <p>1 Q. And that's what you did in your 2 report for purposes of looking at cumulative 3 NDMA exposure, correct?</p> <p>4 A. Correct.</p> <p>5 Q. You took the NDMA calculation that 12:58 PM 6 Hidajat gave and made assumptions for hours 7 of employment, work weeks, work weeks and 8 breathing rates, correct?</p> <p>9 A. Correct.</p> <p>10 Q. And if we apply those same 12:58 PM 11 assumptions to the total nitrosamine score 12 for cumulative exposures, the cumulative 13 nitrosamine in Quartile II, the numbers that 14 we get are on the order of 24,000 to 51,000 15 micrograms, correct? 12:59 PM</p> <p>16 MR. NIGH: Form objection.</p> <p>17 A. Yeah, I would have to calculate it 18 out. But yeah, I would agree it's a similar 19 calculation times the 48 weeks per year, 40 20 hours per -- you know, work per day and the 12:59 PM 21 breathing rate.</p> <p>22 BY MR. FOWLER:</p> <p>23 Q. Right. And it's just a math 24 problem and in Quartile III cumulative 25 nitrosamine exposure would be on the order of 12:59 PM</p>	<p style="text-align: right;">Page 494</p> <p>1 A. You mean specific patients?</p> <p>2 Q. Correct.</p> <p>3 A. No. No, I didn't get specific 4 patient -- I just had from different types of 5 manufacturers. 01:01 PM</p> <p>6 Q. Right. I think we're on the same 7 page, but let me try to ask the question 8 again just so that we're clear and just so we 9 have a clean record.</p> <p>10 In your work in this case, did you 01:01 PM 11 look at any patient pharmacy records to 12 evaluate what any given plaintiff -- what 13 medications any given plaintiff took and in 14 what quantity and for what duration?</p> <p>15 A. No. 01:01 PM</p> <p>16 Q. And I know from listening to your 17 answers to Mr. Fowler's questions that you 18 have a medical degree, correct?</p> <p>19 A. Yes, correct.</p> <p>20 Q. You're not a licensed physician, 01:01 PM 21 though, true?</p> <p>22 A. Correct.</p> <p>23 Q. And since you're not a licensed 24 physician, I take it you've not treated or 25 examined any of the plaintiffs to this 01:01 PM</p>

<p style="text-align: right;">Page 499</p> <p>1 per million for product code c55523, 2 and these are all way above the FDA 3 allowable -- acceptable intake for NDMA. 4 Q. Do you remember what my question 5 was, sir? 01:07 PM 6 A. I don't know an individual -- I 7 answered -- I don't know by name a particular 8 person, I think. 9 Q. There you go. Thank you. 10 Now, the workers in Quartile II in 01:07 PM 11 the Hidajat study had total nitrosamines 12 exposures between 24 million to 51 million 13 nanograms, right? 14 A. I would have to calculate it out, 15 but it seems reasonable that it's a similar 01:08 PM 16 calculation that I used in my report for 17 NDMA. 18 Q. Well, we've been talking in 19 generalities. So let me see if I can get 20 specific and maybe that will help us. 01:08 PM 21 Do you agree that the occupational 22 exposures in Hidajat, where workers were 23 exposed for years and years and years to tens 24 of millions of nanograms of nitrosamines, is 25 not at all representative of the nitrosamine 01:08 PM</p>	<p style="text-align: right;">Page 501</p> <p>1 A. Correct. 2 Q. And, in fact, I think if you take 3 a look at page 10 of your report, that's 4 where we'll find a mention of my client, 5 right? 01:10 PM 6 A. Yes. Yes. 7 Q. And at page 10 of your report, one 8 of the things you suggest is that Mylan had 9 NDMA ranging from .01 parts per million to 10 .09 parts per million that was reported." 01:10 PM 11 Did I read that correctly? 12 A. Yes. 13 Q. So if we assume that someone was 14 taking Mylan's valsartan at the maximize 15 daily dose of 320 milligrams per day, the 01:11 PM 16 NDMA content in that medication was no more 17 than 3 to 28 nanograms per day, correct? 18 MR. NIGH: Form objection. 19 A. Correct. 20 BY MR. TRISCHLER: 01:11 PM 21 Q. That's far below the acceptable 22 intake level of 96 nanograms set by the FDA, 23 though, right? 24 A. Correct. My understanding is -- 25 Q. By the way, when we were talking 01:11 PM</p>
<p style="text-align: right;">Page 500</p> <p>1 levels observed in the valsartan-containing 2 medications at issue? Can we agree on that 3 simple fact? 4 A. Well, as said in my report, I 5 quantified the amount of -- using the Hidajat 01:09 PM 6 paper and their quartiles and the 7 calculation, I quantified the amount of NDMA 8 that those rubber workers were exposed to. 9 And this was a study with 36,000 people over 10 a 49-year follow up 01:09 PM 11 Q. Okay. Then let's -- if you're not 12 able to give me a simple yes to that then 13 maybe we can get specific. 14 I told you I represent Mylan. 15 You're familiar with my client, right? 01:09 PM 16 A. Yes. 17 Q. You reviewed data from testing 18 that was conducted to determine nitrosamine 19 levels in some of Mylan's 20 valsartan-containing medications, right? 01:09 PM 21 A. Correct. 22 Q. And you've been -- you discussed 23 that data in your report and you've mentioned 24 it a few times in response to some of my 25 questions here today, right? 01:10 PM</p>	<p style="text-align: right;">Page 502</p> <p>1 about Hidajat and we mentioned that the 2 exposures in Hidajat were on the order of 3 tens of millions of nanograms, that was a 4 cumulative yearly exposure not over a 5 lifetime, right? 01:11 PM 6 MR. NIGH: Form objection. 7 A. Correct. My understanding is that 8 there are people who had -- they went to the 9 pharmacy and had different -- different 10 valsartan batches, so there was not only 01:11 PM 11 Mylan, they may have gone to the pharmacy and 12 then gotten another valsartan tablet from a 13 different -- 14 BY MR. TRISCHLER: 15 Q. Well, in fairness, sir, you told 01:12 PM 16 me you haven't reviewed any patient day, you 17 haven't reviewed any medical records, you 18 haven't talked to any patient, you haven't 19 looked at any pharmacy records, you're just 20 speculating right now. 01:12 PM 21 MR. NIGH: Form objection. 22 BY MR. TRISCHLER: 23 Q. Right? 24 A. Okay. I'm not following the 25 question, though. 01:12 PM</p>